REMARKS

Claims 31-40, 42-49 and 53 currently appear in this application. The Office Action of February 27, 2004, has been carefully studied. These claims define novel and unobvious subject matter under Sections 102 and 103 of 35 U.S.C., and therefore should be allowed. Applicants respectfully request favorable reconsideration, entry of the present amendment, and formal allowance of the claims.

Claims 29-30 and 50-52 are rejected under 35 U.S.C. 102(e) as being anticipated by Holmes-Farley.

As the present amendment cancels claims 29-30 and 50-52, this rejection is now moot.

Claims 31-32, 36, 41-43 and 49 are rejected under 35 U.S.C. 102(a) as being unpatentable over Holmes-Farley et al. '754 in view of Sato et al. Holmes-Farley et al. are said to disclose the method of preparing crosslinked phosphate-binding polymers in oral formulations for the treatment of hypercholesterolemia. Holmes-Farley does not specify the excipients crystalline cellulose or HPC. Sato et al. are said to teach succinic compounds for oral administration, and

teaches the use of conventional disintegrators such as low-substituted HPC.

This rejection is respectfully traversed. The specification at page 5, lines 3-9, state that they attempted to produce phosphate binding polymer preparations in the form of tablets using the additives described in U.S. 5,496,545, but that the tablets did not have a sufficient hardness, rapid disintegration and dispersibility, and ability to bind to phosphate. The additives in the '545 patent are lactose, dextrose, sucrose, sorbitol, mannitol, starches, gum acacia, alginates, tragacanth, gelatin, calcium silicate, microcrystalline cellulose, polyvinylpyrrolidone, cellulose, methyl cellulose, methylhydroxybenzoates, propylhydroxybenzoates, and talc.

In order to produce tablets with an acceptable hardness, the present inventors discovered that if the particles have an average particle size of no more than 400 microns and a true specific gravity of 1.20-1.22, with a water content of 1-14%, tablets of adequate hardness can be produced, even using microcrystalline cellulose as disclosed in Holmes-Farley et al. '545. Claim 31 calls for particles of a phosphate-binding polymer having an average particle size of

no more than 400 microns, with at least 90% being occupied by particles no larger than 500 microns, and having a true specific gravity of 1.20-1.22 and a water content of 1-14%. Table 1 on page 13 of the specification as filed makes it clear that no tablets made solely from the phosphate-binding polymer with a true specific gravity of 1.253 had adequate hardness. However, tables produced solely from the phosphate-binding polymer with a true specific gravity of 1.211 had adequate hardness. Holmes-Farley et al. '754 are completely silent with respect to hardness of the tablets vs. specific gravity of the particles used to make the tablets.

Sato et al. add nothing to Holmes Farley et al. '754. Sato et al. merely teach that conventional carriers for tablets include microcrystalline cellulose with conventional disintegrators such as low-substituted HPC. This does not suggest to one skilled in the art that a satisfactory tablet can be produced from a phosphate-binding polymer using these carriers, because the present inventors found that, in order to produce a tablet with adequate hardness, the particles of the phosphate-binding polymer must have a certain specific gravity, water content, and particle size.

There is nothing in Sato et al. that would lead one reading Holmes-Farley et al. '754 to use particles having a specific particle size and a certain true specific gravity to make tablets having adequate hardness.

Tablets produced according to the present invention, which have a specific gravity of 1.20-1.22 and a water equivalent of 1-14%, with most particles being no larger than 500 microns, have high hardness, low weight loss, and high disintegrating properties. It is only when the properties of the particles are controlled that a satisfactory tablet can be produced, and there is nothing in Holmes-Farley et al. '754 or Sato et al. that suggest making tablets form particles having these properties.

Holmes-Farley et al. '754 do not discloses any specific physical characteristics of the particles used to make tablets. Although Holmes-Farley et al. '754 produced a phosphate-binding polymer accidentally by use of a water/acetonitrile mixed solvent, they did not realize that there was a difference in true specific gravity between a polymer thus produced and one produced using only water as a solvent. There is no teaching in Holmes-Farley et al. '754

that the polymer produced using water/acetonitrile solvent is superior for making into tablets.

In view of the above, it is respectfully submitted that the claims are now in condition for allowance, and favorable action thereon is earnestly solicited.

Respectfully submitted,

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